

§ 803.21

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(2) If you are an importer, you must submit MDR reports to:

(i) The manufacturer and to us, no later than 30 calendar days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or

(ii) The manufacturer, no later than 30 days calendar after receiving information that a device you market has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(3) If you are a manufacturer, you must submit MDR reports to us:

(i) No later than 30 calendar days after the day that you become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(ii) No later than 30 calendar days after the day that you become aware of information that reasonably suggests a device has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur; or

(iii) Within 5 work days if required by § 803.53.

(c) What kind of information reasonably suggests that a reportable event has occurred?

(1) Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(2) If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Persons

qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers. You must keep in your MDR event files (described in § 803.18) the information that the qualified person used to determine whether or not a device-related event was reportable.

§ 803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?

(a) The MEDWATCH Medical Device Reporting Code Instruction Manual contains adverse event codes for use with FDA Form 3500A. You may obtain the coding manual from CDRH's Web site at <http://www.fda.gov/cdrh/mdr/373.html>; and from the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850, FAX: 301-443-8818, or e-mail to DSMICA@CDRH.FDA.GOV.

(b) We may sometimes use additional coding of information on the reporting forms or modify the existing codes. If we do make modifications, we will ensure that we make the new coding information available to all reporters.

§ 803.22 What are the circumstances in which I am not required to file a report?

(a) If you become aware of information from multiple sources regarding the same patient and same reportable event, you may submit one medical device report.

(b) You are not required to submit a medical device report if:

(1) You are a user facility, importer, or manufacturer, and you determine that the information received is erroneous in that a device-related adverse event did not occur. You must retain documentation of these reports in your MDR files for the time periods specified in § 803.18.

(2) You are a manufacturer or importer and you did not manufacture or import the device about which you have adverse event information. When you receive reportable event information in error, you must forward this information to us with a cover letter explaining that you did not manufacture or import the device in question.